

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James C. KENNEDY et al.

Title: PHOTOCHEMOTHERAPEUTIC METHOD USING 5-

AMINOLEVULINIC ACID AND OTHER PRECURSORS

OF ENDOGENOUS PORPHYRINS

Appl. No.: 10/663,992

Filing Date: 09/17/2003

Examiner: Unassigned

Art Unit: 1614

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Mail Stop PATENT APPLICATION Commissioner for Patents PO Box 1450 Alexandria, Virginia 22313-1450

Sir:

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in parent application Serial No. 09/928,505, filed 08/14/2001. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The relevance of the listed documents is explained in the parent application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Data

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March 2004

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Respectfully submitted,

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Substitute for form 1449B/PTO		Complete if Known	
M)FORMATION DISCLOSURE	Application Number	10/663,992	
、 1004 S是ATEMENT BY APPLICANT	Filing Date	09/17/2003	
MAR Dette Submitted: March 11, 2004	First Named Inventor	James C. KENNEDY	
Dave Submitted, Warch 11, 2004	Group Art Unit	1614	
h se as many sheets as necessary)	Examiner Name	Unassigned	
Sheet 1 of 4	Attorney Docket Number	067286-0275	

				U.S. PATENT DOCUMENTS	3	
Examiner Initials*	Cite No.1	U.S. Patent De	ocument	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document	Pages, Columns, Lines, Where Relevant
iniuais	140.	Number	Kind Code ² (if known)	Gred Boodingh	MM-DD-YYYY	Passages or Relevant Figures Appear
	A1	4,772,681		FUKUDA, et al.	09/1988	
	A2	4,925,736		SHIKOWITZ	05/1990	
	A3	4,932,934		DOUGHERTY, et al.	06/1990	
	A4	4,977,177		BOMMER, et al.	12/1990	
	A5	5,004,811		BOMMER, et al.	04/1991	
	A6	5,079,262		KENNEDY, et al.	01/1992	
	A7	5,127,938		REBEIZ	07/1992	
	A8	5,163,990		REBEIZ	11/1992	
_	A9	5,200,427		REBEIZ, et al.	04/1993	
	A10	5,211,938		KENNEDY, et al.	05/1993	
	A11	5,219,878		RINGUET, et al.	06/1993	
	A12	5,234,940		KENNEDY, et al.	08/1993	
	A13	5,226,907		TANKOVICH	07/1993	
	A14	5,422,093		KENNEDY, et al.	06/1995	
	A15	5,423,803		TANKOVICH, et al.	06/1995	
	A16	5,425,728		TANKOVICH	06/1995	
	A17	5,484,803		RICHTER	01/1996	
	A18	5,705,518		RICHTER ET AL.	01/1998	

					FC	DREIGN PATENT DOCUMEN	TS		
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	A19	EP	0 233 701				08/1987		
	A20	WO	91/01727				02/1991		
	A21	wo	93/08715		,		05/1993		1
	A22	wo	93/20810				10/28/1993		
	A23	wo	94/106424				03/31/1994		
	A24	WO	94/12239				06/09/1994		
	A25	WO	95/07077				03/1995		
	A26	WO	95/05813				03/02/1995		
	A27	wo	95/31189		_		11/23/1995		

		NON PATENT LITERATURE DOCUMENTS	
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Sheet	2	of	4	Attorney Docket Number	067286-0275	

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	A28	BOEHNCKE, et al., Treatment of Psoriasis by Topical Photodynamic Therapy with Polychromatic Light, <i>The Lancet</i> , 343:801, March 1994.	
	A29	FUKUDA et al., Photodynamic Action of Endogenously synthesized Porphyrins from Aminolevulinic, <i>Int. J. Biochem.</i> , 25:10; 1395-98, 1993.	
	A30	LOH et al., Endogenous Porphyrin Distribution-Induced by 5-Aminolaevulinic Acid, <i>J. Photochem. Photobiol.</i> , 20:47-54, 1993.	
	A31	VAN DER VEEN et al., In Vivo Fluorescence Kinetics and Photodynamic Therapy Using 5-Aminolaevulinic. Br. J. Cancer, 70:867-72, 1994.	
	A32	GRANT et al., Photodynamic Therapy of Normal Rat Arteries After Photosensitisation Using, <i>Br. J. Cancer</i> , 70:72-78, 1994.	
	A33	KENNEDY, "Photochemotherapy - Clinical Aspects", Department of Oncology and Pathology, Photosensitisation. Edited by G. Moreno et al., pp. 453-463, (1988).	T
	A34	KENNEDY, "Photodynamic Therapy With Endogenous Protoporphyrin IX: Basic Principles And Present Clinical Experience", <i>Journal of Photochemistry and Photobiology, B: Biology</i> , Vol. 6:143-148, (1990).	-
	A35	DENNIS et al., "Protection of NIH 3T3 Cells From Infection By Trypomastigotes And Sphaeromastigotes Of J. Trypanosoma Cruzi, Telahuen Strain, By Porphyrins In The Presence And Absence of Light (630 and 690 NM)", Parasitol., Vol. 75(6):970-976, (1989).	
	A36	BERLIN et al., "Normal Pathways, Studied With The Aid of N", <i>The Metabolism of ä-Aminolaevulic Acid</i> , Vol.64:80-99,(1956).	
	A37	BRAULT et al., "Fundamental Aspects In Tumor Photochemotherapy: Interactions Of Porphyrins With Membrane Model Systems And Cells", <i>Biochimie</i> , Vol. 68:913-921, (1986).	
	A38	DIVARIS et al., "Phototoxic Damage To Sebaceous Glands And Hair Follicles Of Mice After Systemic Journal Administration of 5-Aminolevulinic Acid Correlates With Localized Protoporphyrin IX Fluorescence", <i>American of Patbology</i> , Vol. 136(4):891-897, (1990).	
	A39	GROSSMAN, "PDT For Hirsutiem", Lasers Surg. Med. Suppl., Vol. 7:A205, (1995).	T
	A40	MALIK et al., "Topical Appliction of 5-Aminolevulinic Acid, DMSO and EDTA: Protoporphyrin IX Accumulation In Skin And Tumours Of Mice", <i>Journal of Photochemistry And Photobiology B: Biology</i> , Vol. 28:213-218, (1995).	
	A41	KORELL et al., "Einsatz der Photodynamischen Lasertherapie in der Gynaekologie", <i>Gynaekol Geburtshilfliche Rundsch</i> , Vol. 35:90-97, (1995).	T
	A42	UNTCH et al., "Synergistischer Effekt von Delta-Aminolaevulinsaeure und Photodynamischer Lasertherapie Anhand Eines In-Vitro-Modells Mit Dem ATP-Tumorchemosensitivitaetstest", <i>Gynaekol Geburtshilfliche Rundsch</i> , Vol. 35:85-89, (1995).	

Examiner	Date
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	A43	SZEIMIES et al., "Topische Photodynamische Therapie In Der Behandlung Oberflaechlicher Hauttumoren", Hautarzt, Vol. 46:315-318, (1995).	
	A44	WOLF et al., "Photodynamic Therapy With 5-Aminolevulinic Acid:A Promising Concept For The Treatment of Cutaneous Tumors", <i>Dermatology</i> , Vol. 190:183-185, (1995).	
	A45	YANG et al., "Evidence Of Lasting Functional Destruction Of The Rat Endometrium After 5-Aminolevulinic Acid Induced Photodynamic Ablation: Prevention Of Implantation", <i>Am. J. Obstet. Gynecol.</i> , Vol. 168(3):995-1001, (1993).	
	A46	WOLF et al., "Topical Photodynamic Therapy With Endogenous Porphyrins After Application of 5-Aminolevulinic Acid", <i>J. Am. Acad. Dermatol.</i> , Vol. 28:17-21, (1993).	
	A47	GOFF et al., "Effects Of Photodynamic Therapy With Topical Application of 5-Aminolevulinic Acid On Normal Skin Of Hairless Guinea Pigs", <i>J. Photochem. Photobiol. B: Biol.</i> , Vol. 15:239-251, (1992).	
	A48	PENG et al., "Distribution And photosensitizing Efficiency Of Porphyrins Induced by Application Of Exogenous 5-Aminolevulinic Acid In Mice Bearing Mammary Carcinoma", <i>Int. J. Cancer</i> , Vol. 52:433-443, (1992).	
	A49	SUROLIA et al., "De Novo Biosynthesis Of Heme Offers A New Chemotherapeutic Target In The Human Malarial Parasite", <i>Biochemical And Biophysical Research Communications</i> , Vol. 187(2):744-750, (1992).	
	A50	VAN HILLEGERSBERG et al., "Selective Accumulation Of Endogenously Produced Porphyrins In A Liver Metastasis Model in Rates", <i>Gastroenterology</i> , Vol. 103:647-651, (1992).	
	A51	FUKUDA et al., "Tumour-Localizing Properties Of Porphyrins. in vivo Studies Using Free And Liposome Encapsulated Aminolevulinic Acid", <i>Comp. Biochem. Physiol.</i> , Vol. 102B(2):433-436, (1992).	
	A52	BEDWELL et al., "Fluorescence Distribution And Photodynamic Effect Of ALA-Induced PP IX In The DMH Rat Colonic Tunour Model", <i>Br. J. Cancer</i> , Vol. 65:818-824, (1992).	
	A53	REBEIZ et al., "Photodestruction of Tumor Cells By Induction Of Endogenous Accumulation Of Protoporphyrin IX: Enhancement By 1,10-Phenanthroline", <i>Photochemistry and Photobiology</i> , Vol. 55(3):431-435, (1992).	
	A54	ANDREONI et al., "Effects of HpD And Laser On Transformed and Corresponding Normal Cultured Cells: Differential Cytotoxicity As An In Vitro Model For Tumor Photochemotherapy", <i>Porphyrins In Tumor Phototherapy</i> , pp.143-155, (1983).	
	A55	ROBINO et al., "Porphyrin Metabolism In Human Neoplastic Tissues", Panminerva Medica, pp. 290-92.	

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	A56	SAMSOEN M., Arsenal Medicamenteux Dermatologique, Pg.603-606, ISSN. 0752-5370 (1995) (Abstract).			
	A57	POTTIER et al., "Non-Invasive Technique for Obtaining Fluorescence Excitation and Emission Spectra In Vivo", <i>Photochemistry and Photobiology</i> , Vol. 44, No. 5, pp 679-687, (1986).			
	A58	MANDELL ET AL., Principles and Practice of Infectious Diseases, 4 th ed. 1995, pp. 1388, 1393-1396.			
	A59	N. NAVONE ET AL., "Porphyrin biosynthesis in human breast cancer. Preliminary mimetic <i>in vitro</i> studies", <i>Med. Sci. Res.</i> , 1988, Vol. 16, pp. 61-62, Buenos Aires, Republica Argentina.			

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